UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

WANDA MATHIS	CIVIL ACTION NO. 06-0825
VERSUS	JUDGE S. MAURICE HICKS, JR.
E.I. DUPONT DE NEMOURS & CO. AND MENTOR CORPORATION	MAGISTRATE JUDGE HORNSBY

MEMORANDUM RULING

Before the Court is a Motion for Summary Judgment (Record Document 57) filed by defendant Mentor Corporation ("Mentor"). For the reasons set forth below, Mentor's Motion for Summary Judgment is **GRANTED**.

I. BACKGROUND.[1]

A. Facts.

In January 1984, plaintiff Wanda Mathis ("Mathis") underwent surgery to have her thyroid removed. Following the surgery, her vocal cords were paralyzed and she did not speak for approximately one year. In December 1984, Mathis underwent a procedure in which Polytef, a paste containing Teflon, was injected into her throat to stabilize her vocal cords and restore her voice functionality. The primary mechanism by which Polytef accomplishes the goal of stabilizing paralyzed vocal cords is by promoting the growth of

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[1]Plaintiff Wanda Mathis ("Mathis") filed a statement of disputed material facts. See Record Document 67-3. However, the filing does not dispute the facts set forth in Mentor's statement of undisputed material facts, but only restates and reiterates the basic facts set forth in the complaint and then attempts to challenge Mentor's preemption analysis and legal interpretation of Medtronic v. Lohr, 518 U.S. 470, 116 S.Ct. 2240 (1996). Accordingly, this Court has adopted much of Mentor's statement of undisputed material facts. See Local Rule 56.2 and Ragas v. Tennessee Gas Pipeline Co., 136 F.3d 455, 458 (5th Cir. 1998) ("The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his or her claim.").

benign fibrous connective tissue in the area of the injection. See Record Document 57-3, Exhibit 1 (Affidavit of Clarke Scherff, Vice President of Regulatory Compliance/Quality Assurance and Compliance Officer for Mentor), ¶ 4.

In November 2004, Mathis complained of difficulty in breathing and her doctor diagnosed her as having a Teflon granuloma in her throat. Mathis' granuloma was surgically removed.

In 2006, Mathis filed the instant lawsuit against Mentor, alleging liability under the Louisiana Products Liability Act ("LPLA") and negligence for failure to warn her of the risks associated with Polytef injectable vocal cord paste.

B. History of Polytef.

Polytef is a paste made of equal parts of Teflon polytetrafluoroethylene powder and glycerin, with polysorbate added. See id., ¶ 6. Doctors have injected Teflon paste into paralyzed vocal cords to restore voice functionality since at least 1962.

Polytef was first manufactured by Ethicon, Inc. ("Ethicon"). Ethicon transferred ownership of Polytef to Mentor O & O, Inc. in 1982. In 1990, Mentor acquired the assets of Mentor O & O, Inc., including the right to manufacture and distribute Polytef. In 2006, Mentor sold its Polytef product line to Coloplast. See id., ¶ 5.

Pursuant to United States Food and Drug Administration ("FDA") regulation, Polytef underwent rigorous FDA review prior to its introduction into the United States market. See id., ¶ 7. Before the enactment of the Medical Device Amendments ("MDA") in 1976, the regulatory scheme in place required that the FDA review occur by way of the New Drug Application ("NDA") process, which required Ethicon to provide the FDA with a body of information to establish the safety and effectiveness of Polytef. See id., ¶¶ 8-9. Such

information included completion of animal, pre-clinical and clinical trials with scores of qualified investigators and hundreds of case reports evaluated; over a thousand pages of data regarding information about the physical and chemical properties of Polytef; details of each step in the manufacturing process along with corresponding test methods; and a bibliography of the relevant scientific and medical literature related to Polytef. See id., ¶¶ 10-11. Further, all of the product labeling, including the package insert, was subject to mandatory review and approval by the FDA. See id., ¶ 12.

In 1966, Ethicon submitted data regarding Polytef to the FDA for review. See id., ¶ 13. Over the next several years, Ethicon provided the FDA with additional data that was required for the NDA process. The amended NDA for Polytef was submitted to the FDA on December 15, 1971 and contained details of animal studies, manufacturing and quality control procedures, possible side effects, summaries of surgical cases during the investigational use of Polytef and, later, clinical trials, and post-operative complications, including Teflon granulomas. See id., ¶ 14. On January 20, 1972, the FDA notified Ethicon that Polytef was approved for use:

> We have completed the review of this application as amended and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Id., Exhibit 1-A (Letter to Ethicon from FDA) at 1. Polytef was specifically approved for vocal cord injection to restore voice functionality. See id., ¶ 16. The FDA approval of Polytef allowed Ethicon, Mentor O & O, Inc., and Mentor to sell Polytef commercially in the United States, as long as they conformed to the FDA imposed conditions under which the sale was approved. See id., ¶ 17. FDA conditions also required that Polytef be sold with the precise packaging and labeling approved by FDA during the NDA process. See id., ¶

19. At all times during and since the Polytef NDA approval, Ethicon, Mentor O & O, Inc., and Mentor have complied with the applicable FDA rules and regulations. See id., ¶ 17.

C. Background and Purpose of the Medical Device Amendments.[2]

Congress passed the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetics Act ("the Act") in 1976. See id., ¶ 20. The Act places each medical device into one of three classes depending on the degree of risk the device poses to the public. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 476, 116 S.Ct. 2240, 2246 (1996), citing 21 U.S.C. §§ 360c- 360k. Devices are designated to Class I and subject only to minimal regulation by "general controls" if they present no unreasonable risk of illness or injury. See Medtronic, 518 U.S. at 476- 477, 116 S.Ct. at 2246. Class II devices are potentially more harmful and, although they can be marketed without prior approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." See id. at 477, 116 S.Ct. at 2246. Class III is reserved for devices that "either presen[t] a potential unreasonable risk of illness or injury, or which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." See id. (internal marks omitted). The manufacturer of a new Class III device must provide the FDA with a "reasonable assurance" that the device is both safe and effective through the rigorous premarket approval ("PMA") process before the device may be introduced to the market. See id.

Polytef and similar devices that were classified and approved as new drugs through

[2]This section of the Memorandum Ruling is adopted from the Court's ruling in Charles David Rousseau v. Depuy Orthopaedics, Inc. and Howmedica Osteonics, Corp., Civil Action No. 06-517 (Record Document 60).

the NDA process, prior to the enactment of the MDA, were described as "transitional devices." Record Document 57-3, Exhibit 1, ¶ 20. The devices were automatically designated as Class III medical devices under the MDA. See id., ¶ 21. Such devices were deemed to have PMA approval if they had completed the NDA approval process. See id., ¶ 22; see also 21 U.S.C. § 360j(l)(3)(A). As with all Class III devices, Ethicon, Mentor O & O, Inc., and Mentor had a continuing obligation to provide certain information to the FDA on a regular basis. See id., ¶ 24. Any changes in the product, including labeling, must be and were approved by FDA. See id., ¶ 25. Polytef was sold only with packaging and package inserts that included specific language required by FDA. See id., ¶ 26. Mentor was not permitted to change the packaging or package inserts unless directed to do so by, or after obtaining express approval from, the FDA. See id., ¶ 27.

II. LAW AND ANALYSIS.

A. Summary Judgment Standard.

Summary judgment is proper pursuant to Rule 56 of the Federal Rules of Civil Procedure "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986). "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 263 (5th Cir. 2002). If the movant

demonstrates the absence of a genuine issue of material fact, "the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial." Littlefield v. Forney Indep. Sch. Dist., 268 F.3d 275, 282 (5th Cir. 2001). Where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the nonmovant, then summary judgment should be granted. See Alton v. Tex. A&M Univ., 168 F.3d 196, 199 (5th Cir. 1999).

B. Mathis' Negligence and LPLA Claims.

Suing in negligence and under the LPLA, Mathis alleges that Mentor failed to warn her adequately of the hazards associated with the use of Polytef and/or concealed its knowledge of these hazards from her and others. See Record Document 49, ¶ 15. The LPLA provides the exclusive theories of liability against manufacturers for damages caused by their products, stating:

> This Chapter establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter. Conduct or circumstances that result in liability under this Chapter are "fault" within the meaning of Civil Code Article 2315.

La. R.S. 9:2800.52. Under the LPLA, "the manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. R.S. 9:2800.54(A). The LPLA further provides that "a product is unreasonably dangerous if and only if:

> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
> (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;

> (3) ***The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R.S. 9:2800.57***; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

La. R.S. 9:2800.54(B) (emphasis added). Claims against manufacturers that are outside the scope of the LPLA are routinely dismissed. See Jefferson v. Lead Industries Ass'n, Inc., 106 F.3d 1245, 1248 (5th Cir. 1997); Brown v. R.J. Reynolds Tobacco Co., 852 F.Supp. 8 (E.D. La. 1994), *aff'd*, 52 F.3d 524 (5th Cir. 1995); Grenier v. Medical Engineering Corp., 99 F.Supp.2d 759 (W.D. La. 2000), *aff'd*, 243 F.3d 200 (5th Cir. 2001).

In the Second Amended Petition for Damages, Mathis alleges that Mentor "directly or indirectly manufactured, assembled, designed, labeled, packaged, distributed, marketed, advertised, distributed and/or sold [Polytef] in the State of Louisiana." Record Document 49, ¶ 14. Mentor does not dispute its status as a manufacturer under the LPLA. Accordingly, the LPLA provides the exclusive theories of recovery available to Mathis in this matter and her claims against Mentor for negligence, which are set forth in paragraphs 23-29 of the Second Amended Petition for Damages, are outside the scope of the LPLA and must be dismissed. See Grenier, 99 F. Supp. 2d at 763. Summary judgment in favor of Mentor is therefore granted as to Mathis' negligence claims.

The Court will now turn to Mathis' claims under the LPLA, which Mentor argues are preempted. Mentor contends that because Polytef was approved through the rigorous NDA process and was deemed to have PMA approval, every detail of Polytef and its packaging has been approved by the FDA. Thus, Mentor argues, state law claims alleging that these specifications are inadequate would conflict with the FDA's determination and

are therefore preempted by federal law. Conversely, Mathis asserts that her claims are not preempted "because the FDA has issued no device-specific regulations regarding the design, manufacturing, or labeling of injectable [P]olytef paste, and because [her] state law claims are based on laws of general applicability." Record Document 67-2 at 15.

1. Preemption Analysis.[3]

Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." Medtronic, 518 U.S. at 474 (citing the preamble to the Medical Device Amendments of 1976, 90 Stat. 539). The MDA's preemption provision, 21 U.S.C. § 360k(a), governs the extent to which the MDA preempts state law. It reads:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Id. The FDA has also promulgated regulations interpreting Section 360k, which state:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

In 1993, the Fifth Circuit Court of Appeals, in a case involving a device approved

[3]Again, much of the Court's preemption analysis is adopted from its previous ruling in Charles David Rousseau v. Depuy Orthopaedics, Inc. and Howmedica Osteonics, Corp., Civil Action No. 06-517 (Record Document 60).

through the PMA process, held that Section 360k preempted the state law liability claim. See Stamps v. Collagen Corp., 984 F.2d 1416, 1422 (5th. Cir.1993). Later, in a 1996 decision, Lohr, the Supreme Court held that a product liability claim was not preempted under Section 360k. See Medtronic, 518 U.S. 470, 116 S.Ct. 2240. In Martin v. Medtronic, Inc., 254 F.3d 573, 577 (5th. Cir. 2001), the Fifth Circuit examined the Supreme Court's decision in Lohr and discussed the decision's effect on the Fifth Circuit's prior holding in Stamps. The Fifth Circuit noted that Lohr involved a device approval process far less specific and rigorous than the PMA process. See Martin, 254 F.3d at 575. In Lohr, the device was approved through the § 510(k) notification process which is an exception to the more demanding PMA process. See id. at 576. The Supreme Court even noted "[t]he § 510(k) notification process is by no means comparable to the PMA process." Id. at 577, citing Medtronic, 518 U.S. at 478-479, 116 S.Ct. at 2247. The Fifth Circuit distinguished Stamps from Lohr and reasoned that Lohr's holding only applied to devices approved by the Section 510k process, not devices approved through the PMA process. See Martin, 254 F.3d at 583-584. In sum, the Fifth Circuit held that the Supreme Court did not overrule its prior holding in Stamps regarding PMA-approved products. See Martin, 254 F.3d at 584.

The Fifth Circuit further clarified its Martin analysis in Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919 (5th Cir. 2006). The court stated that this circuit uses the Martin/Lohr test to analyze products liability claims against PMA-approved devices. See id. at 930. The test requires a court to analyze the claims and determine whether the duties enforced by such claims would threaten the federal duties imposed by the PMA process. See id. The court found that the negligent design and defective design claims

were preempted because the FDA studied and approved the device's design through the PMA process. See id. Likewise, the FDA approved the labeling, warnings, instructions, and training process for the device during the PMA process, thus any claims of inadequacy in any of these areas were also preempted. See id. at 931.[4]

2. Application of Preemption Analysis to Mathis' LPLA Claims.

Unlike the devices at issue in the cases examined by the Supreme Court and the Fifth Circuit, Polytef was approved through the NDA process before the passage of the MDA and the establishment of the PMA process. However, the MDA provides that such devices are deemed to have completed the PMA process. See 21 U.S.C. § 360j(l)(3)(A). Since Polytef is deemed to have been approved through the PMA process, this court will analyze the claims accordingly.

In performing the preemption analysis, both the Supreme Court and the Fifth Circuit focus on the process the product underwent in order to obtain FDA approval. See Medtronic, 518 U.S. at 493-94, 116 S.Ct. at 2254-2255; Martin, 254 F.3d at 575; and Gomez, 442 F.3d at 930. As set forth in the background section of this Memorandum Ruling, the FDA reviewed and approved the design, chemical composition, and manufacturing process for Polytef. See Record Document 57-3, Exhibit 1 at ¶¶ 7-11. This review included the product labeling, namely instructions for use and warnings. See id. at ¶ 12. Ethicon, Mentor O & O, Inc., and Mentor were required to distribute and market Polytef only in compliance with these specific federal requirements. Further, as with all

[4]A more detailed analysis of Lohr, Martin, and Gomez is set forth in the Court's ruling in Charles David Rousseau v. Depuy Orthopaedics, Inc. and Howmedica Osteonics, Corp., Civil Action No. 06-517 (Record Document 60).

Class III devices, Ethicon, Mentor O & O, Inc., and Mentor were under a continuing obligation to provide certain information to the FDA on a regular basis and any changes in the product, including its labeling, had to be approved by the FDA. See id. at ¶¶ 24-25.

Here, the aforementioned FDA review was not a generic or cursory review of Polytef. Rather, the FDA performed a comprehensive and rigorous review that was device-specific. In light of the conditions of approval imposed, the continuing obligation to provide the FDA with certain information, and the prohibition against modifying the design, manufacturing process, or labeling without FDA approval, it is clear that there are specific federal requirements applicable to Polytef. In continuing its preemption analysis under Section 360k, the Court is now required "to look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether they threaten the federal PMA process requirements." Gomez, 442 F.3d at 93031.

Pursuant to the LPLA, Mathis has alleged that Mentor failed to warn her of the risks associated with Polytef. The FDA approved Polytef's labeling and warnings through the NDA process.[5] That process required the FDA to review the results of pre-clinical and clinical trials, evaluate case reports, examine data regarding information about the physical and chemical properties of Polytef, and analyze the manufacturing process. Further, all of the product labeling, including the package insert, was reviewed and approved by the

[5]Polytef was approved through the NDA process before the passage of the MDA and the establishment of the PMA process. However, the MDA provides that such devices are deemed to have completed the PMA process. See 21 U.S.C. § 360j(l)(3)(A). Since Polytef is deemed to have been approved through the PMA process, this court will analyze the claims accordingly.

FDA. Specifically, the FDA was aware of possible side effects and post-operative complications, including Teflon granulomas, and still approved the label and warnings that issued with Polytef. To permit Mathis' claims that warnings material "the FDA required and approved . . . were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations." Gomez, 442 F.3d at 931. Thus, Mathis' inadequate warning claims are preempted under 21 U.S.C. § 360k(a) and summary judgment in favor of Mathis is awarded as to Mathis' claims under the LPLA.

III. CONCLUSION.

Based on the foregoing analysis, Mentor's Motion for Summary Judgment (Record Document 57) is **GRANTED**. All claims by Mathis against Mentor are hereby **DISMISSED WITH PREJUDICE**.

A judgment consistent with the terms of this Memorandum Ruling shall issue herewith.

THUS DONE AND SIGNED at Shreveport, Louisiana, this 16th day of January, 2008.

S. MAURICE HICKS, JR.
UNITED STATES DISTRICT JUDGE